

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of Barry S. Goldman *et al.*

Art Unit: 1631

Serial No.: 09/902,540

Examiner: Carolyn L. Smith

Filed: July 10, 2001

For: Myxococcus xanthus Genome Sequences
and Uses Thereof

APPELLANT'S BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal from the Final Rejection of claims 11 and 43-46 in the above-described patent application. Notice of Appeal in this application was received at the Patent & Trademark Office on March 8, 2004, setting the period for filing the brief to expire on May 8, 2004. Enclosed herewith is a petition for extension of time of two months, extending the period for filing this brief to July 8, 2004. The statutory fee of \$330 for filing a brief in support of an appeal is paid via the enclosed Fee Transmittal. This Brief is submitted in triplicate.

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

Certificate of Mailing: The undersigned certifies that this Brief is transmitted to the USPTO in an envelope addressed to the Commissioner at the above address with first class postage on July 8, 2004

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Handwritten signature: J. E. [unclear], Reg No. 29,938

2. Related Appeals and Interferences

The Appellant is unaware of any Appeals of Interferences related to this Appeal.

3. Status of Claims

Claims 1, 8, 11-13, 17-19 and 38-46 were pending and finally rejected at the time of appeal. Claims 14-16, 27-28, 30-31 and 34-37 were withdrawn from consideration. Submitted herewith is an amendment canceling claims 1, 8, 12-13, 17-19 and 38-42 for the purpose of simplifying issues on appeal. Thus, the only claims in this appeal are claims 11 and 43-46.

4. Status of Amendments

Aside from the Amendment canceling claims submitted concurrently with this brief, no other Amendment/Response has been filed subsequent to Final Rejection.

5. Summary of Invention

The invention as claimed is directed to a substantially purified nucleic acid molecule encoding a nitrate reductase (claim 11), recombinant DNA constructs for expression of a nitrate reductase (claims 43-45) and plant cells comprising such recombinant DNA construct (claim 46). As more specifically stated in claim 11 the purified nucleic acid molecule is characterized by the nitrate reductase with amino acid sequence comprising SEQ ID NO: 11926.

6. Issues

The sole issues in this Appeal is whether claims 11 and 43-46 are unpatentable under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Grouping of claims

All claims stand or fall together. A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

The Office acknowledges in the Final Office Action that

“The specification discloses SEQ ID NO:4639 which corresponds to DNA encoding a protein of SEQ ID NO:11926. SEQ ID NOs:4639, and its full-length complement, and 11926 meet the written description provisions of 35 U.S.C. 112, first paragraph.”

Office Action, page 4

Appellant traverses the position of the Office that

“Due to the open claim language wording of “comprising” and comprises” as cited in claims .. 11 (line 2) ... 43 (line 2); “having” of claim ... 43(line 3) and claim 44 (line 2) ... these claims and any dependent claims therefrom encompass gene sequences that do not meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. “

Office Action, page 4

“Therefore, only SEQ ID NO:4639, its full length complement, and nucleic acids specifically encoding 11926 but not the full breadth of claims 1, 8, 11-13, 17-19 and 38-46 meet the written description provision of 35 U.S.C. 112, first paragraph.”

Office Action, page 5

It appears to appellant that the basis for the rejection is that the claims cover a large genus of purified nucleic acid molecules and DNA constructs and plant cells with recombinant DNA constructs all based on the characteristic of DNA that encodes a nitrite reductase with identical or homologous to the amino acid sequence of SEQ ID NO:11926. Appellant submits that this large number alone cannot be the proper basis for a written description rejection of a “comprising” claim. If it was, every comprising claim ever allowed

in a granted patent would be invalid for failing to describe every nuance of the claimed invention.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID No.1192, and therefore, the claimed invention.

Nor was this standard altered by the recent decision of the Federal Circuit in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.2d 1316, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002) (reprinted at 323 F.3d 956 (Fed. Cir. 2002); or the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement; 66 Fed. Reg. 1099 *et seq.* ("Written Description Guidelines"). To the contrary, the holding in *Enzo Biochem* emphasized that "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.' " *Enzo Biochem*, 323 F.3d at 963. More recently, however, the Federal Circuit has expressed that the written description requirement does not require that Applicants recite "the precise 'structure, formula, chemical name, or physical

properties' required by *Lilly*." *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320, 66 U.S.P.Q.2d 1429, 1438 (Fed. Cir. 2003), *rehearing denied* (Apr. 25, 2003); *Petition for Certiorari Filed*, 72 U.S.L.W. 3106 (Jul. 24, 2003) (NO. 03-124). Rather, *Moba* reemphasized that "[t]he test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing. . . [t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. . . ' " *Moba*, 352 F.3d at 1320-1321, *quoting Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 U.S.P.Q.2d 1227, 1232 (Fed. Cir. 2000).

Appellants have provided the amino acid sequence required by the claims, *i.e.*, SEQ ID No:11926, and have thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences does not mean that Appellants were any less in possession of the claimed nucleic acid molecules. It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

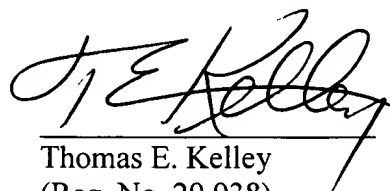
Furthermore, the present application describes more than just the nucleic acid molecule that encodes the nitrite reductase of SEQ ID No.11926. Appellants have

provided written description of “substantially purified” nucleic acid molecules at page 7 of the specification which instructs a person of ordinary skill in the art that the molecule is separated from substantially all other molecules normally associated with it in its native state, e.g. may be greater than 60% free from other molecules present in the natural mixture. Thus, additional nucleotides are clearly contemplated. Moreover, Appellants have provided a written description of the elements of recombinant DNA constructs and transgenic plants comprising such constructs throughout the specification, see especially pages 20-27. Thus, a large genus of recombinant DNA constructs and plant cells have not only been contemplated but described to a person of ordinary skill in the art. In addition, claims to homologues are a fundamental aspect of biotechnology patents; see applicants description of homologues at page 16. Thus, recombinant DNA constructs comprising molecules that encode homologous nitrite reductase with high amino acid identity to SEQ ID NO:11926 was not only contemplated but disclosed to a person of ordinary skill in the art.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the final rejection of the appealed claims.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'T.E. Kelley', is written over a horizontal line.

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APPENDIX A

Claims on Appeal

WHAT IS CLAIMED IS:

11. (Twice amended) A substantially purified nucleic acid molecule encoding a nitrite reductase comprising SEQ ID NO:11926.

43. (Added) A recombinant DNA construct for expression of a nitrite reductase gene in a plant cell, wherein said construct comprises a promoter functional in a plant cell operatively linked to a molecule encoding a nitrite reductase protein having at least 70 percent sequence identity to SEQ ID NO:11926 over the entire length of said protein.

44. (Added) The recombinant DNA construct of claim 43, wherein said nucleic acid molecule encodes a nitrite reductase protein having at least 90 percent sequence identity to SEQ ID NO:11926 over the entire length of said protein.

45. (Added) The recombinant DNA construct of claim 43, wherein said nucleic acid molecule encodes a nitrite reductase comprising SEQ ID NO:11926.

46. (Added) A plant cell comprising a recombinant DNA construct of claim 43.